



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,671	04/24/2000	Michael Stephen Austin	99-0138	7622

7590 08/15/2002

Boston Scientific Corporation
Attn William J Shaw
One Boston Scientific Place
Mail Stop C15
Natick, MA 01760-1537

EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,671

Applicant(s)

AUSTIN, MICHAEL STEPHEN

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 April 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-38, drawn to an endoluminal prosthesis, classified in class 623, subclass 1.19.
 - II. Claims 39-40, drawn to a method for fabricating an endoluminal prosthesis, classified in class 623, subclass 901.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process such as by molding.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Bill Shaw on August 2, 2002 a provisional election was made without traverse to prosecute the invention of I, claims 1-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39 and 40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

5. The information disclosure statement filed April 24, 2000 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently

Art Unit: 3731

understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "25" has been used to designate both perpendicular plane and straight segment. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "26" has been used to designate both a curved stent and the parallel projection. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 24. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

9. The disclosure is objected to because of the following informalities:

On page 6 line 26, change "Figs. 8C and 8C" to --Figs. 8B and 8C--.

On page 7 line 22, change "Figs. 13D and 13E" to --Figs. 13C and 13D--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2-6 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recite the limitation "the body segment" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 4-6 recite the limitation "the stent body" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the wire" in line 1. There is insufficient antecedent basis for this limitation in the claim. The lack of antecedent basis occurs because the claim is stated to depend from claim 20. Examiner believes that this claim is meant to depend from claim 10 and has examined it as if it depended from claim 10.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 8-16, 21, 23-32, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,994,071 to MacGregor.

Art Unit: 3731

Regarding claims 1, 8, 9, 23, 24, and 25, MacGregor discloses a prosthesis comprising a hollow tubular body comprising at least one segment of curvature (see FIGS 2A-3D and Column 2 lines 32-49).

Regarding claim 2, MacGregor discloses that the body segment is curved in at least one plane (see FIGS 2A-3D).

Regarding claims 10-15 and 26-31, MacGregor discloses that the hollow tubular body comprises undulating wire (see FIG. 1 loops 12) formed from a shape memory alloy, a super elastic alloy, a polymer, or nitinol (see Column 5 lines 39-51).

Regarding claims 16 and 32, MacGregor discloses that the wire is uniformly displaced along the length of the body (see FIG. 1 loops 12 and lattice 16).

Regarding claims 21 and 37, MacGregor discloses that at least one branch of the prosthesis extends away from the body of the prosthesis (see FIG. 1 lattices 20 and 22).

Regarding claim 38, MacGregor discloses a medical implant comprising at least one segment of curvature (see FIGS. 2A – 3D).

14. Claims 1-9, 17, 21, 23-25, 33 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/09585 to Caro et al.

Regarding claim 1, 8, 9, and 23-25, Caro discloses a prosthesis comprising a hollow tubular body comprising at least one segment of curvature (see FIG. 5 tubing 1).

Regarding claim 2, Caro discloses that the body segment is curved in at least one plane (see FIG. 5 tubing 1).

Regarding claim 3, Caro discloses that the body segment is curved in at least two planes (see Page 5 line 33 – Page 6 line 1).

Art Unit: 3731

Regarding claim 4, Caro discloses that the body segment has at least two segments of curvature located in successive progression along the body and are curved in the same plane (see Page 4 lines 5-27).

Regarding claim 5, Caro discloses that the body has at least two segments of curvature located in successive progression and curved within different planes (see Page 4 lines 5-27).

Regarding claim 6, Caro discloses that the body has at least two segments of curvature that overlap at least a portion of one another and are curved in different planes of curvature (see Page 4 lines 5-27).

Regarding claim 7, Caro discloses segments of curvature that overlap and segments of curvature that do not overlap (see Page 4 lines 5-27).

Regarding claims 17 and 33, Caro discloses that the hollow tubular body comprises a thin-walled tubular material (see page 4 lines 12-19).

Regarding claims 21 and 37, Caro discloses that the prosthesis comprises a branch that extends away from the body of the prosthesis (see FIG. 2A).

15. Claims 1, 2, 4, 8, 9, 10, 18, 19, 21-26, 34, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,653,743 to Martin.

Regarding claim 1, 8, 9, and 23-25, Martin discloses a prosthesis comprising a hollow tubular body with at least one segment of curvature (see FIG. 5).

Regarding claim 2, Martin discloses that the body segment is curved in at least one plane (see FIG. 5 prosthesis 1).

Regarding claim 4, Martin discloses that the body has at least two segments of curvature located in successive progression and are curved within the same plane of curvature (see FIG. 5 prosthesis 1).

Art Unit: 3731

Regarding claims 10 and 26, Martin discloses that the body comprises wire (see Column 2 lines 49-60).

Regarding claims 18 and 34, Martin discloses at least one taper along the length of the body (see FIG. 1 prosthesis 1).

Regarding claims 19 and 35, Martin discloses at least one aperture on the body between the proximal end and the distal end (see FIG. 1 opening 7).

Regarding claims 21 and 37, Martin discloses that at least one branch of the prosthesis extends away from the body of the prosthesis (see FIG. 5 graft 18).

Regarding claim 22, Martin discloses that at least a portion of the prosthesis is covered with a graft covering (see Column 2 lines 49-63).

16. Claims 1, 20, 23, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,156,619 to Ehrenfield.

Ehrenfield discloses a prosthesis comprising a hollow tubular body comprising at least one segment of curvature (see FIG. 4 and Column 2 lines 36-39) and at least one non-circular cross-section along the length of the body (see FIG. 4 flange 33).

17. Claims 1, 20, 23, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,695,517 to Marin et al.

Marin discloses a prosthesis comprising a hollow tubular body comprising at least one segment of curvature (see FIG. 3 graft 46 L) and at least one non-circular cross-section along the length of the body (see Column 3 lines 24-33).

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3731

The following patents are cited to further show the state of the art with respect to intraluminal prosthesis and stents:

U.S. Patent No. 5,104,404 to Wolff

U.S. Patent No. 5,133,732 to Wiktor

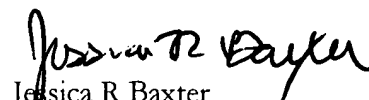
U.S. Patent No. 5,843,120 to Israel et al.

U.S. Patent No. 5,843,175 to Frantzen

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



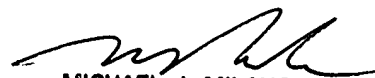
Jessica R Baxter

Examiner

Art Unit 3731

jrb

August 6, 2002



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700